2:21-cv-03181-RMG Date Filed 05/09/25 Entry Number 40-3 Page 1 of 17

# EXHIBIT C

Hereditary Cancer Test



CONFIDENTIAL

Integrated BRACAnalysis® with MyRisk™ Hereditary Cancer Test

### MyRisk Genetic Result

RECEIVING HEALTHCARE PROVIDER

Frederick Dold, MD
Alliance Cancer Specialists
1311 BRISTOL PIKE STE 100
BENSALEM, PA 19020

**SPECIMEN** 

Specimen Type: Blood

Draw Date: Jan 14, 2025

Accession Date: Jan 15, 2025

Report Date: Jan 29, 2025

PATIENT

Legal Name: Speers, Clinton

Date of Birth:

Patient ID:

Sex at Birth: M

Accession #: 05257804-BLD

Requisition #: 11829189



#### GENETIC RESULT: MUTATION IDENTIFIED WITH SPECIAL INTERPRETATION







Other clinical factors may influence individualized management. This analysis may be incomplete if details about cancer diagnoses, ages, family relationships or other factors were omitted or ambiguous. If this patient also has a clinically significant mutation, the recommendations based on the clinical history analysis should be considered in light of the possibility that this mutation explains all or some of the cancer history in the family.

GENE	MUTATION	INTERPRETATION
FH	c.1431_1433dup (p.Lys477dup)	Carrier
	Heterozygous ,	

### DETAILS ABOUT: FH c.1431\_1433dup (p.Lys477dup): NM\_000143.3

Functional Significance: Suspected Deleterious - Abnormal Protein Production and/or Function

The heterozygous germline FH variant c.1431\_1433dup is predicted to result in the duplication of lysine at amino acid position 477 of the FH protein (p.Lys477dup). This variant has been reported in rare cases of isolated renal cancer but is absent from other large studies of patients with renal cancer (Forde et al. Eur Urol Oncol 3:764-772, 2020; Gupta et al. Hum Mutat 42:1362-1364, 2021; Zhang et al. Hum Mutat 41:103-109, 2020). In addition to this equivocal clinical evidence, the common frequency in the general population (http://gnomad.broadinstitute.org) provides insufficient evidence to demonstrate that the p.Lys477dup variant causes Hereditary Leiomyomatosis and Renal Cell Carcinoma syndrome (HLRCC). Taken together, this variant is not expected to be associated with HLRCC and screening for cancers associated with HLRCC is not indicated.

### Clinical Significance: Carrier

Although this variant has not been shown to cause HLRCC, it has been detected in patients with clinical features of the recessive condition, fumarate hydratase deficiency (FHD) when a second pathogenic variant in the FH gene is also present (Coughlin et al. Mol Genet Metab 63:254-262, 1998; Pollard et al. Hum Mol Genet 14:2231-2239, 2005; Deschauer et al. Mol Genet Metab 88:146-52, 2006). Therefore, this patient is considered a carrier of FHD. FHD is characterized by severe neonatal and early infantile encephalopathy usually leading to death in childhood. Two mutations within the FH gene, one inherited from each parent, are required for an individual to have symptoms of FHD. There are no known risks of FHD in individuals carrying a single gene mutation. The biological children of this patient are at risk for FHD if the other parent is also a carrier of a pathogenic FH variant. Screening the other biological parent of any children for FH variants and genetic counseling to discuss reproductive risks may be appropriate.





### MyRisk Genetic Result

Name: Speers, Clinton

DOB

Accession #: 05257804-BLD

Report Date: Jan 29, 2025

### ADDITIONAL FINDINGS: NO VARIANT(S) OF UNCERTAIN SIGNIFICANCE (VUS) IDENTIFIED

Details About Non-Clinically Significant Variants: All individuals carry DNA changes (i.e., variants), and most variants do not increase an individual's risk of cancer or other diseases. When identified, variants of uncertain significance (VUS) are reported. Likely benign variants (Favor Polymorphisms) and benign variants (Polymorphisms) are not reported and available data indicate that these variants most likely do not cause increased cancer risk. Present evidence does not suggest that non-clinically significant variant findings be used to modify patient medical management beyond what is indicated by the personal and family history and any other clinically significant findings.

Variant Classification: Myriad's myVision™ Variant Classification Program performs ongoing evaluations of variant classifications. In certain cases, healthcare providers may be contacted for more clinical information or to arrange family testing to aid in variant classification. When new evidence about a variant is identified and determined to result in clinical significance and management change, that information will automatically be made available to the healthcare provider through an amended report.

### **ADDITIONAL INFORMATION**

Genes Analyzed: Sequencing (seq) and large rearrangement analyses were performed for all coding exons in the following genes, unless otherwise indicated:

APC, ATM, AXIN2, BAP1, BARD1, BMPR1A, BRCA1, BRCA2, BRIP1, CDH1, CDK4, CDKN2A, CHEK2, CTNNA1, FH, FLCN, HOXB13 (seq only), MEN1, MET, MLH1, MSH2, MSH3 (excluding repetitive portions of exon 1), MSH6, MUTYH, NTHL1, PALB2, PMS2, PTEN, RAD51C, RAD51D, SDHA, SDHB, SDHC, SDHD, SMAD4, STK11, TP53, TSC1, TSC2, VHL.

Limited promoter regions may also be analyzed for large rearrangements.

Sequencing (seq) and/or large rearrangement (LR) analyses were performed only for the gene portions indicated in parenthesis for the following genes:

EGFR (exons 18-21, seq and LR), EPCAM (exons 8-9, LR only), GREM1 (exon 1 and upstream regulatory regions, LR only), MITF (c.952, seq only), POLE (exonuclease domain, seq only), POLD1 (exonuclease domain, seq only), RET (exons 5, 8, 10, 11, 13-16 seq and LR), TERT (promoter region 71 bases upstream of the translation start, c.-71\_-1, seq only).

\*\* Other genes not analyzed with this test may also be associated with cancer.

Indication for Testing: It is our understanding that this individual was identified for testing due to a personal or family history suggestive of a hereditary predisposition for cancer.

Patient Information: Sex assigned at birth is a label given to an individual at birth, typically "male" or "female". In this report, the terms "male", "female", "he", "she", "woman", and "man" refer to sex assigned at birth.

Associated Cancer Risks and Clinical Management: The "MyRisk Management Tool" associated with this report provides a summary of cancer risk and professional society medical management guidelines that may be useful in developing a plan for this patient based on any clinically significant test results and/or reported personal/family history. In some cases, a MyRisk Management Tool cannot be provided, such as when the result has a special interpretation or includes a mutation with unusual characteristics.

Analysis Description: The Technical Specifications summary (myriad.com/technical-specifications) describes the analysis, method, performance, nomenclature, and interpretive criteria of this test. Current testing technologies are unable to definitively determine whether a variant is germline or somatic in origin, which may significantly impact risk estimates and medical management; therefore, these results should be correlated with this patient's personal and family history. The interpretation of this test may also be impacted if the patient has a hematologic malignancy or an allogeneic bone marrow transplant.

### CLASSIFICATION DISCLAIMER

THE CLASSIFICATION AND INTERPRETATION OF ALL VARIANTS IDENTIFIED IN THIS ASSAY REFLECTS THE CURRENT STATE OF MYRIAD'S SCIENTIFIC UNDERSTANDING AT THE TIME THIS REPORT WAS ISSUED. VARIANT CLASSIFICATION AND INTERPRETATION MAY CHANGE FOR A VARIETY OF REASONS, INCLUDING BUT NOT LIMITED TO, IMPROVEMENTS TO CLASSIFICATION TECHNIQUES, AVAILABILITY OF ADDITIONAL SCIENTIFIC INFORMATION, AND OBSERVATION OF A VARIANT IN MORE PATIENTS.



Date Filed 05/09/25

Entry Number 40-3

Page 4 of 17

CONFIDENTIAL



56322166

MyRisk Genetic Result

Name: Speers, Clinton

DOB:

Accession #: 05257804-BLD

Report Date: Jan 29, 2025

Please contact Myriad Medical Services at 1-800-469-7423 X 3850 to discuss any questions regarding this result.

These test results should only be used in conjunction with the patient's clinical history and any previous analysis of appropriate family members. The patient's clinical history and test results should not be disclosed to a third party, unless related to treatment or payment for treatment, without the patient's express written authorization. It is strongly recommended that these results be communicated to the patient in a setting that includes appropriate genetic consultation. This test was developed and its performance characteristics determined by Myriad Genetic Laboratories. It has not been cleared or approved by the U.S. Food and Drug Administration (FDA). The FDA has determined that clearance or approval for laboratory-developed tests is not required.

This Authorized Signature pertains to this laboratory report:

Benjamin B. Roa, PhD Diplomate ABMGG Laboratory Director Genetic testing was complated by CLIA and CAP accredited laboratories in the United States located at: 320 Wakara Way, Salt Lake City, UT 84108 and 322 N 2200 W, Salt Lake City, UT 84116 CLIA IDs: 46D0880690, 46D2275645

The following personnel codes and laboratory director signature may reflect remote review of digital data: 1857, 3028

8hips R

Myriad genetics

© 2025 Myriad Genetics, Inc. | PH: 1-800-469-7423 FX: 801-584-3615
The format and contents of this report are proprietary and may not be copied or used without permission, except for purposes of diagnosing, counseling and treating the patient identified in the report and members of their family. Myriad, Myriad Myrisk, RiskScore, RRACAnalysis, COLARIS, myVision and their respective logos are either trademarks or registered trademarks of Myriad Genetics, Inc. in the United States and other jurisdictions.



## Integrated BRACAnalysis® with MyRisk™ Hereditary Cancer Test Clinical & Cancer Family History Information



RECEIVING HEALTHCARE PROVIDER

Frederick Dold, MD
Alliance Cancer Specialists
1311 BRISTOL PIKE STE 100
BENSALEM, PA 19020

**SPECIMEN** 

Specimen Type: Blood

Draw Date: Jan 14, 2025

Accession Date: Jan 15, 2025

Report Date: Jan 29, 2025

PATIENT

Legal Name: Speers, Clinton

Date of Birth:

Patient ID:

Sex at Birth: M

Accession #: 05257804-BLD

Requisition #: 11829189

PERSONAL / FAMILY CANCER HISTORY SUMMARY				
FAMILY MEMBER	CANCER / CLINICAL DIAGNOSIS	AGE AT DIAGNOSIS		
Patient	Other	64		
Father	Melanoma	70		

The clinical information displayed here was provided by a qualified healthcare provider on the Test Request Form and other documents, and was not verified by Myriad. Female relatives refers to sex assigned at birth, which is a label given to an individual at birth, typically "male" or "female". Family members listed as "other" are not included in a Tyrer-Cuzick breast cancer risk estimate or other personal/family history assessments. For more information see the Specifications for Personal/Family History Analysis at http://myriad.com/technical-specifications.

The accuracy and completeness of the information provided in the Clinical and Cancer Family History Information section of the report (e.g. height and weight, age of menarche) may significantly affect the accuracy of breast cancer risk estimates provided based on either Tyrer-Cuzick or RiskScore. The impact of breast surgeries and hormone therapy (except hormone replacement therapy) have not been assessed or validated for Tyrer-Cuzick and RiskScore.

RiskScore is not valid, and may significantly over- or under-estimate breast cancer risk for individuals who do not meet the eligibility criteria in effect when the testing was performed. The current criteria are: 1) sex assigned at birth is female 2) age is 18 to 84 years, 3) no personal history of breast cancer, LCIS, hyperplasia (with or without atypia), or a breast biopsy with unknown results, 4) there is no mutation detected in a breast cancer risk gene (other than a monoallelic CHEK2 mutation in a White/Non-Hispanic or Ashkenazi Jewish individual), 5) the individual's relatives have not been found to have a mutation in a high-penetrance breast cancer risk gene (BRCA1, BRCA2, CDH1, PALB2, PTEN, STK11, TP53, a biallelic mutation in CHEK2, or the specific mutation c.7271T>G (p.Val2424Gly) in ATM) and 6) the sample was submitted with a current Test Request Form and the ordering healthcare provider has not determined that RiskScore is inappropriate for the patient. If this is an amended report for a patient tested in the past, please refer to the MyRisk Technical Specifications at http://myriad.com/technical-specifications for the eligibility criteria in effect at the time of the original testing.



MyRisk\*

Hereditary Cancer Test



Frederick Dold, MD

BENSALEM, PA 19020

Alliance Cancer Specialists

1311 BRISTOL PIKE STE 100

CONFIDENTIAL

Integrated BRACAnalysis® with MyRisk™ Hereditary Cancer Test

### MyRisk Management Tool

SPECIMEN

Specimen Type: Blood

Draw Date: Jan 14, 2025

Accession Date: Jan 15, 2025

Jan 29, 2025 Report Date:

PATIENT

Legal Name: Speers, Clinton

Date of Birth:

Patient ID

Sex at Birth:

Accession #: 05257804-BLD Requisition #: 11829189



#### GENETIC RESULT: MUTATION IDENTIFIED WITH SPECIAL INTERPRETATION





### CLINICAL HISTORY ANALYSIS: BASED ON THE CLINICAL HISTORY PROVIDED, MODIFIED MEDICAL MANAGEMENT GUIDELINES IDENTIFIED



Other clinical factors may influence individualized management. This analysis may be incomplete if details about cancer diagnoses, ages, family relationships or other factors were omitted or ambiguous. If this patient also has a clinically significant mutation, the recommendations based on the clinical history analysis should be considered in light of the possibility that this mutation explains all or some of the cancer history in the family.

G	E	N	E

#### MUTATION

### THIS GENETIC TEST RESULT IS ASSOCIATED WITH THE **FOLLOWING CANCER RISKS:**

FH

c.1431\_1433dup (p.Lys477dup) Heterozygous

Insufficient data to assess the impact of this finding on cance risk. See the Genetic Test Result for more information.

Please see the Genetic Test Result for more details on any variant(s) detected in this patient, including variant classification information.

The terms "male", "female", "he", "she", "women", and "men" refer to sex assigned at birth.

### ADDITIONAL FINDINGS: NO VARIANT(S) OF UNCERTAIN SIGNIFICANCE (VUS) IDENTIFIED

### WHAT ARE THE PATIENT'S CANCER RISKS?

These risk tables show the clinically significant cancer risks identified as part of this patient's testing. Testing for some patients does not include some of the analyses listed:

- GENETIC RESULT: Mutations detected in any of the hereditary cancer genes included on the MyRisk panel.
- BREAST CANCER RISKSCORE: RiskScore estimate of remaining lifetime breast cancer risk if 20% or greater
- CLINICAL HISTORY ANALYSIS for breast cancer risk: Tyrer-Cuzick model estimate of remaining lifetime breast cancer risk of 20% or
- · CLINICAL HISTORY ANALYSIS for breast, colorectal, pancreatic, prostate and melanoma cancer: Analysis of the patient's personal and family history.

The risks for each of these results are provided separately. If the risk for any individual cancer is affected by more than one of these results, the risk associated with each finding is listed in a separate table. At this time, there is not enough information to estimate risks for cancers affected by more than one gene mutation, or risks based on both gene mutations and personal/family history.

### Risks Identified From the Clinical History Analysis for Breast, Colorectal, Prostate, Pancreatic and Melanoma Cancer

The risk(s) below were identified based on information provided by the healthcare provider who ordered this patient's testing. This





### MyRisk Management Tool

Name: Speers, Clinton

DOB:

Accession #: 05257804-BLD

Report Date: Jan 29, 2025

information is listed on the Clinical & Cancer Family History Information page of the report.

IMPORTANT NOTE REGARDING THE CLINICAL HISTORY ANALYSIS: If this patient, or any of this patient's relatives, has a gene mutation associated with the risk for any of the cancers listed below, it is likely, but not certain, that the personal/family history is due to that mutation. Therefore, the risks listed here may not apply to this patient. Genetic testing of additional family members may be helpful in these situations.

CANCER TYPE	CANCER RISK	RISK FOR GENERAL POPULATION	RELATED TO
MELANOMA			
To age 80	Elevated Risk	1.6%	Family History

### WHAT MANAGEMENT FOR CANCER RISKS SHOULD BE CONSIDERED?

This overview of clinical management guidelines is based on the patient's genetic test results and the Clinical History Analysis. Medical management guidelines are summarized from established medical societies, primarily the National Comprehensive Cancer Network (NCCN). If there are overlapping management guidelines for any individual cancer due to more than one of these results, the guidelines associated with each finding are listed in separate tables, even if they are the same. At this time, there are no medical society guidelines for how to adjust management when there are multiple sources of risk, such as from more than one gene mutation, or a mutation and a personal/family history of cancer. In these cases, it may be appropriate to use the most aggressive of the management options provided.

The overview provided below should not be used as the sole source of information to determine medical management. The references cited should always be consulted for more details and updates to the recommendations.

No information is provided related to treatment of a previous or existing cancer or polyps. The recommendation summaries below may require modification due to the patient's personal medical history, past surgeries and other treatments. Patients with a past history of cancer, benign tumors, or pre-cancerous findings may be candidates for long term surveillance and risk-reduction strategies beyond what is necessary for the treatment of their initial diagnosis. Any discussion of medical management options is for general information purposes only and does not constitute a recommendation. While genetic testing and medical society recommendations provide important and useful information, medical management decisions should be made in consultation between each patient and his or her healthcare provider.

### Management Options Based on the Clinical History Analysis

The management options below are based on medical society guidelines for individuals with personal/family histories suggesting an increased risk for breast, colorectal, prostate, melanoma and pancreatic cancers.

IMPORTANT NOTE REGARDING RECOMMENDATIONS RELATED TO THE CLINICAL HISTORY ANALYSIS: In most cases, these recommendations will not apply if this patient, or any of this patient's relatives, has a gene mutation association with the risk for any of the cancers listed below.

PROCEDURE	AGE TO BEGIN	FREQUENCY Unless otherwise indicated by findings	RELATED TO	
MELANOMA  Consider available risk-reduction strategies, such as	Mala de la			
frequent self-examination of the skin, consideration of		ALV:	e 4 ic.	

Consider available risk-reduction strategies, such as frequent self-examination of the skin, consideration of clinical skin examinations, and minimizing exposure to the sun and other sources of UV radiation. <sup>1,2</sup>

Individualized

NA

Family History

- 1. Cancer.Net, American Society of Clinical Oncology, Melanoma: Risk Factors and Prevention 12/2021 Available at http://www.cancer.net/cancer-types/melanoma/risk-factors-and-prevention.
- 2. National Council on Skin Cancer Prevention. At https://skincancerprevention.org/learning/risk-factors/what-causes-melanoma-skin-cancer/ (accessed on 03-24-2023)





\_

MyRisk Management Tool

DOB: I

Accession #: 05257804-BLD

Report Date: Jan 29, 2025

**Notes for Personalized Management:** 

### INFORMATION ON HOW CANCER RISKS AND MANAGEMENT ARE DETERMINED

The MyRisk Management Tool provides cancer risk levels based on analysis of genetic test results (see MyRisk Genetic Result) and a summary of medical society management recommendations based on both the genetic test results and a limited analysis of the patient's clinical history related to the risk for breast, colorectal, prostate, melanoma and pancreatic cancers. Here are some important points to understand as you interpret this test report and decide on the best plan for management:

- Comprehensive patient management. The management recommendations presented in this report are a summary of management options recommended by the National Comprehensive Cancer Network (NCCN) and other established medical societies and are general in nature. The patient's actual management should be modified based on personal medical history, surgeries and other treatments. A comprehensive risk assessment and management plan may take into account this report and other aspects of the patient's personal/family medical history (e.g., all known clinical diagnoses), as well as lifestyle, environmental and other factors.
- Risk estimates based on provider-supplied information. Some of the risk estimates and management recommendation summaries
  provided in this report are based on our interpretation of information supplied by the ordering health care provider on the test request
  form (see Specifications for Personal/Family History analysis at myriad.com/technical-specifications). The patient's actual risks and
  appropriate management may be significantly different if details provided for cancer diagnoses, ages, family relationships or other factors
  were incorrect, omitted, ambiguous or have since changed. Please review the clinical history listed on the Clinical & Family History
  Information page of this report to make sure that the information used was provided and interpreted correctly.
- Variability in Tyrer-Cuzick risk estimates. Tyrer-Cuzick estimates of breast cancer risk can vary significantly based on the way in which the
  model is used, and the estimate provided here may be higher or lower than what would be calculated by other users. For complete
  details of how Myriad calculates Tyrer-Cuzick risk estimates, including how Myriad handles information provided in a format not
  compatible with the model, please see the Specifications for Personal/Family History analysis at myriad.com/technical-specifications.
  These Specifications also include information for recalculating the Tyrer-Cuzick breast cancer risk estimate if desired.
- What is meant by "High Risk" and "Elevated Risk"? In the Genetic Test Result Summary, a gene-associated cancer risk is described as "High Risk" for a cancer type if all of the following conditions are met: the absolute risk of cancer is approximately 5% or higher, the increase in risk over the general population is approximately 2 to 3-fold or higher, and there is significant data from multiple studies supporting the cancer risk estimate. A gene is described as "Elevated Risk" for a cancer type if there is sufficient data to support an increase in cancer risk over the general population risk, but not all criteria for "High Risk" are met.

### INFORMATION FOR FAMILY MEMBERS

Family members should talk to their healthcare providers about hereditary cancer testing to help define their own risk and assist in the interpretation of this patient's genetic test result.

- This patient's relatives are at risk for carrying the same mutation(s) and associated cancer risks as this patient. Cancer risks for individuals
  who have this/these mutation(s) are provided below.
- Family members should talk to a healthcare provider about genetic testing. Close relatives such as parents, children, and siblings have the highest chance of having the same mutation(s) as this patient. Other more distant relatives such as cousins, parents siblings, and grandparents also have a chance for carrying the same mutation(s). Testing of at-risk relatives can identify those family members with the same mutation(s) who may benefit from surveillance and early intervention. More resources for family testing are available at MySupport360.com.



**Entry Number 40-3** 

Page 9 of 17

CONFIDENTIAL



MyRisk Management Tool

Name: Speers, Clinton

DØB:

Accession #: 05257804-BLD

Report Date: Jan 29, 2025

Please contact Myriad Medical Services at 1-800-469-7423 X 3850 to discuss any questions regarding this result.

**END OF MANAGEMENT TOOL** 



### PATIENT COPY CONFIDENTIAL

Integrated BRACAnalysis® with MyRisk™ Hereditary Cancer Test

### MyRisk Genetic Result

RECEIVING HEALTHCARE PROVIDER

Frederick Dold, MD Alliance Cancer Specialists 1311 BRISTOL PIKE STE 100 BENSALEM, PA 19020 **SPECIMEN** 

Specimen Type: Blood

Draw Date: Jan 14, 2025

Accession Date: Jan 15, 2025

Report Date: Jan 29, 2025

PATIENT

Legal Name: Speers, Clinton

Hereditary Cancer Test

Date of Birth:

Patient ID:

Sex at Birth: M

Accession #: 05257804-BLD

Requisition #: 11829189



### GENETIC RESULT: MUTATION IDENTIFIED WITH SPECIAL INTERPRETATION





### CLINICAL HISTORY ANALYSIS: BASED ON THE CLINICAL HISTORY PROVIDED, MODIFIED MEDICAL MANAGEMENT GUIDELINES IDENTIFIED



Other clinical factors may influence individualized management. This analysis may be incomplete if details about cancer diagnoses, ages, family relationships or other factors were omitted or ambiguous. If this patient also has a clinically significant mutation, the recommendations based on the clinical history analysis should be considered in light of the possibility that this mutation explains all or some of the cancer history in the family.

AND RESIDENCE TO SHARE SHARE SHARE	THE RESERVE AND ADDRESS OF THE PARTY OF THE	THE RESERVE AND ADDRESS OF THE PARTY OF THE
GENE	MUTATION	INTERPRETATION
		IIII KE SALIO

FH

c.1431\_1433dup (p.Lys477dup) Heterozygous

Carrier

### DETAILS ABOUT: FH c.1431\_1433dup (p.Lys477dup): NM\_000143.3

Functional Significance: Suspected Deleterious - Abnormal Protein Production and/or Function

The heterozygous germline FH variant c.1431\_1433dup is predicted to result in the duplication of lysine at amino acid position 477 of the FH protein (p.Lys477dup). This variant has been reported in rare cases of isolated renal cancer but is absent from other large studies of patients with renal cancer (Forde et al. Eur Urol Oncol 3:764-772, 2020; Gupta et al. Hum Mutat 42:1362-1364, 2021; Zhang et al. Hum Mutat 41:103-109, 2020). In addition to this equivocal clinical evidence, the common frequency in the general population (http://gnomad.broadinstitute.org) provides insufficient evidence to demonstrate that the p.Lys477dup variant causes Hereditary Leiomyomatosis and Renal Cell Carcinoma syndrome (HLRCC). Taken together, this variant is not expected to be associated with HLRCC and screening for cancers associated with HLRCC is not indicated.

### Clinical Significance: Carrier

Although this variant has not been shown to cause HLRCC, it has been detected in patients with clinical features of the recessive condition, fumarate hydratase deficiency (FHD) when a second pathogenic variant in the FH gene is also present (Coughlin et al. Mol Genet Metab 63:254-262, 1998; Pollard et al. Hum Mol Genet 14:2231-2239, 2005; Deschauer et al. Mol Genet Metab 88:146-52, 2006). Therefore, this patient is considered a carrier of FHD. FHD is characterized by severe neonatal and early infantile encephalopathy usually leading to death in childhood. Two mutations within the FH gene, one inherited from each parent, are required for an individual to have symptoms of FHD. There are no known risks of FHD in individuals carrying a single gene mutation. The biological children of this patient are at risk for FHD if the other parent is also a carrier of a pathogenic FH variant. Screening the other biological parent of any children for FH variants and genetic counseling to discuss reproductive risks may be appropriate.



PATIENT COPY

CONFIDENTIAL



### MyRisk Genetic Result

Name: Speers, Clinton

DOB:

Accession #: 05257804-BLD

Report Date: Jan 29, 2025

### ADDITIONAL FINDINGS: NO VARIANT(S) OF UNCERTAIN SIGNIFICANCE (VUS) IDENTIFIED

Details About Non-Clinically Significant Variants: All individuals carry DNA changes (i.e., variants), and most variants do not increase an individual's risk of cancer or other diseases. When identified, variants of uncertain significance (VUS) are reported. Likely benign variants (Favor Polymorphisms) and benign variants (Polymorphisms) are not reported and available data indicate that these variants most likely do not cause increased cancer risk. Present evidence does not suggest that non-clinically significant variant findings be used to modify patient medical management beyond what is indicated by the personal and family history and any other clinically significant findings.

Variant Classification: Myriad's myVision<sup>TM</sup> Variant Classification Program performs ongoing evaluations of variant classifications. In certain cases, healthcare providers may be contacted for more clinical information or to arrange family testing to aid in variant classification. When new evidence about a variant is identified and determined to result in clinical significance and management change, that information will automatically be made available to the healthcare provider through an amended report.

### ADDITIONAL INFORMATION

Genes Analyzed: Sequencing (seq) and large rearrangement analyses were performed for all coding exons in the following genes, unless otherwise indicated:

APC, ATM, AXIN2, BAP1, BARD1, BMPR1A, BRCA1, BRCA2, BRIP1, CDH1, CDK4, CDKN2A, CHEK2, CTNNA1, FH, FLCN, HOXB13 (seq only), MEN1, MET, MLH1, MSH2, MSH3 (excluding repetitive portions of exon 1), MSH6, MUTYH, NTHL1, PALB2, PMS2, PTEN, RAD51C, RAD51D, SDHA, SDHB, SDHC, SDHD, SMAD4, STK11, TP53, TSC1, TSC2, VHL.

Limited promoter regions may also be analyzed for large rearrangements.

Sequencing (seq) and/or large rearrangement (L'R) analyses were performed only for the gene portions indicated in parenthesis for the following genes:

EGFR (exons 18-21, seq and LR), EPCAM (exons 8-9, LR only), GREM1 (exon 1 and upstream regulatory regions, LR only), MITF (c.952, seq only), POLE (exonuclease domain, seq only), POLD1 (exonuclease domain, seq only), RET (exons 5, 8, 10, 11, 13-16 seq and LR), TERT (promoter region 71 bases upstream of the translation start, c.-71\_-1, seq only).

\*\* Other genes not analyzed with this test may also be associated with cancer.

Indication for Testing: It is our understanding that this individual was identified for testing due to a personal or family history suggestive of a hereditary predisposition for cancer.

Patient Information: Sex assigned at birth is a label given to an individual at birth, typically "male" or "female". In this report, the terms "male", "female", "he", "she", "woman", and "man" refer to sex assigned at birth.

Associated Cancer Risks and Clinical Management: The "MyRisk Management Tool" associated with this report provides a summary of cancer risk and professional society medical management guidelines that may be useful in developing a plan for this patient based on any clinically significant test results and/or reported personal/family history. In some cases, a MyRisk Management Tool cannot be provided, such as when the result has a special interpretation or includes a mutation with unusual characteristics.

Analysis Description: The Technical Specifications summary (myriad.com/technical-specifications) describes the analysis, method, performance, nomenclature, and interpretive criteria of this test. Current testing technologies are unable to definitively determine whether a variant is germline or somatic in origin, which may significantly impact risk estimates and medical management; therefore, these results should be correlated with this patient's personal and family history. The interpretation of this test may also be impacted if the patient has a hematologic malignancy or an allogeneic bone marrow transplant.

### CLASSIFICATION DISCLAIMER

THE CLASSIFICATION AND INTERPRETATION OF ALL VARIANTS IDENTIFIED IN THIS ASSAY REFLECTS THE CURRENT STATE OF MYRIAD'S SCIENTIFIC UNDERSTANDING AT THE TIME THIS REPORT WAS ISSUED. VARIANT CLASSIFICATION AND INTERPRETATION MAY CHANGE FOR A VARIETY OF REASONS, INCLUDING BUT NOT LIMITED TO, IMPROVEMENTS TO CLASSIFICATION TECHNIQUES, AVAILABILITY OF ADDITIONAL SCIENTIFIC INFORMATION, AND OBSERVATION OF A VARIANT IN MORE PATIENTS.



Date Filed 05/09/25

**Entry Number 40-3** 

Page 12 of 17

PATIENT COPY

CONFIDENTIAL



56322166

MyRisk Genetic Result

Name: Speers, Clinton

DQB:

Accession #: 05257804-BLD

Report Date Jan 29, 2025

Please contact Myriad Medical Services at 1-800-469-7423 X 3850 to discuss any questions regarding this result.

These test results should only be used in conjunction with the patient's dinical history and any previous analysis of appropriate family members. The patient's dinical history and test results should not be disclosed to a third party, unless related to treatment or payment for treatment, without the patient's express written authorization. It is strongly recommended that these results be communicated to the patient in a setting that includes appropriate genetic consultation. This test was developed and its performance characteristics determined by Myriad Genetic Laboratories. It has not been cleared or approved by the U.S. Food and Drug Administration (FDA). The FDA has determined that clearance or approval for laboratory-developed tests is not required.

Genetic testing was completed by CLIA and CAP accredited laboratories in the United States located at: 320 Wakara Way, Salt Lake City, UT 84108 and 322 N 2200 W, Salt Lake City, UT 84116 CLIA IDs: 46D0890690, 46D2275645

The following personnel codes and laboratory director signature may reflect remote review of digital data: 1857, 3028





### PATIENT COPY CONFIDENTIAL

Integrated BRACAnalysis® with MyRisk™ Hereditary Cancer Test Clinical & Cancer Family History Information

MyRisk™ Hereditary Cancer Test

### RECEIVING HEALTHCARE PROVIDER

Frederick Dold, MD
Alliance Cancer Specialists
1311 BRISTOL PIKE STE 100
BENSALEM, PA 19020

#### SPECIMEN

Specimen Type: Blood

Draw Date: Jan 14, 2025

Accession Date: Jan 15, 2025

Report Date: Jan 29, 2025

### PATIENT

Legal Name: Speers, Clinton

Date of Birth:

Patient ID:

Sex at Birth; M

Accession #: 05257804-BLD

Requisition #: 11829189

PERSONAL / FAMILY CANCER HISTORY SUMMARY				
FAMILY MEMBER	CANCER / CLINICAL DIAGNOSIS	AGE AT DIAGNOSIS		
Patient	Other	64		
ather	Melanoma	70		

The clinical information displayed here was provided by a qualified healthcare provider on the Test Request Form and other documents, and was not verified by Myriad. Female relatives refers to sex assigned at birth, which is a label given to an individual at birth, typically "male" or "female". Family members listed as "other" are not included in a Tyrer-Cuzick breast cancer risk estimate or other personal/family history assessments. For more information see the Specifications for Personal/Family History Analysis at http://myriad.com/technical-specifications.

The accuracy and completeness of the information provided in the Clinical and Cancer Family History Information section of the report (e.g. height and weight, age of menarche) may significantly affect the accuracy of breast cancer risk estimates provided based on either Tyrer-Cuzick or RiskScore. The impact of breast surgeries and hormone therapy (except hormone replacement therapy) have not been assessed or validated for Tyrer-Cuzick and RiskScore.

RiskScore is not valid, and may significantly over- or under-estimate breast cancer risk for individuals who do not meet the eligibility criteria in effect when the testing was performed. The current criteria are: 1) sex assigned at birth is female 2) age is 18 to 84 years, 3) no personal history of breast cancer, LCIS, hyperplasia (with or without atypia), or a breast biopsy with unknown results, 4) there is no mutation detected in a breast cancer risk gene (other than a monoallelic CHEK2 mutation in a White/Non-Hispanic or Ashkenazi Jewish individual), 5) the individual's relatives have not been found to have a mutation in a high-penetrance breast cancer risk gene (BRCA1, BRCA2, CDH1, PALB2, PTEN, STK11, TP53, a biallelic mutation in CHEK2, or the specific mutation c.7271T>G (p.Val2424Gly) in ATM) and 6) the sample was submitted with a current Test Request Form and the ordering healthcare provider has not determined that RiskScore is inappropriate for the patient. If this is an amended report for a patient tested in the past, please refer to the MyRisk Technical Specifications at http://myriad.com/technical-specifications for the eligibility criteria in effect at the time of the original testing.



Hereditary Cancer Test



### PATIENT COPY CONFIDENTIAL

Integrated BRACAnalysis® with MyRisk™ Hereditary Cancer Test

### MyRisk Management Tool

RECEIVING HEALTHCARE PROVIDER

Frederick Dold, MD

BENSALEM, PA 19020

Alliance Cancer Specialists 1311 BRISTOL PIKE STE 100 SPECIMEN

Specimen Type: Blood

Draw Date: Jan 14, 2025

Accession Date: Jan 15, 2025

Report Date: Jan 29, 2025

PATIENT

Legal Name: Speers, Clinton

Date of Birth:

Patient 1D:

Sex at Birth: M

Accession #: 05257804-BLD

Requisition #: 11829189



### GENETIC RESULT: MUTATION IDENTIFIED WITH SPECIAL INTERPRETATION





### CLINICAL HISTORY ANALYSIS: BASED ON THE CLINICAL HISTORY PROVIDED, MODIFIED MEDICAL MANAGEMENT GUIDELINES IDENTIFIED



Other clinical factors may influence individualized management. This analysis may be incomplete if details about cancer diagnoses, ages, family relationships or other factors were omitted or ambiguous. If this patient also has a clinically significant mutation, the recommendations based on the clinical history analysis should be considered in light of the possibility that this mutation explains all or some of the cancer history in the family.

### MUTATION

THIS GENETIC TEST RESULT IS ASSOCIATED WITH THE FOLLOWING CANCER RISKS:

FH

c.1431\_1433dup (p.Lys477dup) Heterozygous Insufficient data to assess the impact of this finding on cancer

Please see the Genetic Test Result for more details on any variant(s) detected in this patient, including variant classification information.

The terms "male", "female", "he", "she", "women", and "men" refer to sex assigned at birth.

### ADDITIONAL FINDINGS: NO VARIANT(S) OF UNCERTAIN SIGNIFICANCE (VUS) IDENTIFIED

### WHAT ARE THE PATIENT'S CANCER RISKS?

These risk tables show the clinically significant cancer risks identified as part of this patient's testing. Testing for some patients does not include some of the analyses listed:

- GENETIC RESULT: Mutations detected in any of the hereditary cancer genes included on the MyRisk panel.
- BREAST CANCER RISKSCORE: RiskScore estimate of remaining lifetime breast cancer risk if 20% or greater
- CLINICAL HISTORY ANALYSIS for breast cancer risk: Tyrer-Cuzick model estimate of remaining lifetime breast cancer risk of 20% or greater
- CLINICAL HISTORY ANALYSIS for breast, colorectal, pancreatic, prostate and melanoma cancer: Analysis of the patient's personal and family history.

The risks for each of these results are provided separately. If the risk for any individual cancer is affected by more than one of these results, the risk associated with each finding is listed in a separate table. At this time, there is not enough information to estimate risks for cancers affected by more than one gene mutation, or risks based on both gene mutations and personal/family history.

### Risks Identified From the Clinical History Analysis for Breast, Colorectal, Prostate, Pancreatic and Melanoma Cancer

The risk(s) below were identified based on information provided by the healthcare provider who ordered this patient's testing. This



PATIENT COPY

CONFIDENTIAL



56322166

### MyRisk Management Tool

Name: Speers, Clinton

DOB: F

Accession #: 05257804-BLD

Report Date: Jan 29, 2025

information is listed on the Clinical & Cancer Family History Information page of the report.

IMPORTANT NOTE REGARDING THE CLINICAL HISTORY ANALYSIS: If this patient, or any of this patient's relatives, has a gene mutation associated with the risk for any of the cancers listed below, it is likely, but not certain, that the personal/family history is due to that mutation. Therefore, the risks listed here may not apply to this patient. Genetic testing of additional family members may be helpful in these situations.

CANCER TYPE	CANCER RISK	RISK FOR GENERAL POPULATION	RELATED TO
MELANOMA			
To age 80	Elevated Risk	1.6%	Family History

### WHAT MANAGEMENT FOR CANCER RISKS SHOULD BE CONSIDERED?

This overview of clinical management guidelines is based on the patient's genetic test results and the Clinical History Analysis. Medical management guidelines are summarized from established medical societies, primarily the National Comprehensive Cancer Network (NCCN). If there are overlapping management guidelines for any individual cancer due to more than one of these results, the guidelines associated with each finding are listed in separate tables, even if they are the same. At this time, there are no medical society guidelines for how to adjust management when there are multiple sources of risk, such as from more than one gene mutation, or a mutation and a personal/family history of cancer. In these cases, it may be appropriate to use the most aggressive of the management options provided.

The overview provided below should not be used as the sole source of information to determine medical management. The references cited should always be consulted for more details and updates to the recommendations.

No information is provided related to treatment of a previous or existing cancer or polyps. The recommendation summaries below may require modification due to the patient's personal medical history, past surgeries and other treatments. Patients with a past history of cancer, benign tumors, or pre-cancerous findings may be candidates for long term surveillance and risk-reduction strategies beyond what is necessary for the treatment of their initial diagnosis. Any discussion of medical management options is for general information purposes only and does not constitute a recommendation. While genetic testing and medical society recommendations provide important and useful information, medical management decisions should be made in consultation between each patient and his or her healthcare provider.

### Management Options Based on the Clinical History Analysis

The management options below are based on medical society guidelines for individuals with personal/family histories suggesting an increased risk for breast, colorectal, prostate, melanoma and pancreatic cancers.

IMPORTANT NOTE REGARDING RECOMMENDATIONS RELATED TO THE CLINICAL HISTORY ANALYSIS: In most cases, these recommendations will not apply if this patient, or any of this patient's relatives, has a gene mutation association with the risk for any of the cancers listed below.

PROCEDURE	AGE TO BEGIN	FREQUENCY Unless otherwise indicated by findings	RELATED TO
Consider available risk-reduction strategies, such as frequent self-examination of the skin, consideration of clinical skin examinations, and minimizing exposure to	Individualized	NA	Family History

- 1. Cancer.Net, American Society of Clinical Oncology, Melanoma: Risk Factors and Prevention 12/2021 Available at http://www.cancer.net/cancer-types/melanoma/risk-factors-and-prevention.
- 2. National Council on Skin Cancer Prevention. At https://skincancerprevention.org/learning/risk-factors/what-causes-melanoma-skin-cancer/ (accessed on 03-24-2023)



the sun and other sources of UV radiation. 1,2

PATIENT COPY

CONFIDENTIAL



56322166

MyRisk Management T	iool		
Name: Speers, Clinton	DOB	Accession #: 05257804-BLD	Report Date: Jan 29, 2025
Notes for Personalized Manage	ement:		

### INFORMATION ON HOW CANCER RISKS AND MANAGEMENT ARE DETERMINED

The MyRisk Management Tool provides cancer risk levels based on analysis of genetic test results (see MyRisk Genetic Result) and a summary of medical society management recommendations based on both the genetic test results and a limited analysis of the patient's clinical history related to the risk for breast, colorectal, prostate, melanoma and pancreatic cancers. Here are some important points to understand as you interpret this test report and decide on the best plan for management:

- Comprehensive patient management. The management recommendations presented in this report are a summary of management options recommended by the National Comprehensive Cancer Network (NCCN) and other established medical societies and are general in nature. The patient's actual management should be modified based on personal medical history, surgeries and other treatments. A comprehensive risk assessment and management plan may take into account this report and other aspects of the patient's personal/family medical history (e.g., all known clinical diagnoses), as well as lifestyle, environmental and other factors.
- Risk estimates based on provider-supplied information. Some of the risk estimates and management recommendation summaries
  provided in this report are based on our interpretation of information supplied by the ordering health care provider on the test request
  form (see Specifications for Personal/Family History analysis at myriad.com/technical-specifications). The patient's actual risks and
  appropriate management may be significantly different if details provided for cancer diagnoses, ages, family relationships or other factors
  were incorrect, omitted, ambiguous or have since changed. Please review the clinical history listed on the Clinical & Family History
  Information page of this report to make sure that the information used was provided and interpreted correctly.
- Variability in Tyrer-Cuzick risk estimates. Tyrer-Cuzick estimates of breast cancer risk can vary significantly based on the way in which the
  model is used, and the estimate provided here may be higher or lower than what would be calculated by other users. For complete
  details of how Myriad calculates Tyrer-Cuzick risk estimates, including how Myriad handles information provided in a format not
  compatible with the model, please see the Specifications for Personal/Family History analysis at myriad.com/technical-specifications.
  These Specifications also include information for recalculating the Tyrer-Cuzick breast cancer risk estimate if desired.
- What is meant by "High Risk" and "Elevated Risk"? In the Genetic Test Result Summary, a gene-associated cancer risk is described as "High Risk" for a cancer type if all of the following conditions are met: the absolute risk of cancer is approximately 5% or higher, the increase in risk over the general population is approximately 2 to 3-fold or higher, and there is significant data from multiple studies supporting the cancer risk estimate. A gene is described as "Elevated Risk" for a cancer type if there is sufficient data to support an increase in cancer risk over the general population risk, but not all criteria for "High Risk" are met.

### **INFORMATION FOR FAMILY MEMBERS**

Family members should talk to their healthcare providers about hereditary cancer testing to help define their own risk and assist in the interpretation of this patient's genetic test result.

- This patient's relatives are at risk for carrying the same mutation(s) and associated cancer risks as this patient. Cancer risks for individuals
  who have this/these mutation(s) are provided below.
- Family members should talk to a healthcare provider about genetic testing. Close relatives such as parents, children, and siblings have
  the highest chance of having the same mutation(s) as this patient. Other more distant relatives such as cousins, parents siblings, and
  grandparents also have a chance for carrying the same mutation(s). Testing of at-risk relatives can identify those family members with the
  same mutation(s) who may benefit from surveillance and early intervention. More resources for family testing are available at
  MySupport360.com.



Date Filed 05/09/25

**Entry Number 40-3** 

Page 17 of 17

PATIENT COPY

CONFIDENTIAL



56322166

MyRisk Management Tool

Name: Speers, Clinton

DOB:

Accession #: 05257804-BLD

Report Date: Jan 29, 2025

Please contact Myriad Medical Services at 1-800-469-7423 X 3850 to discuss any questions regarding this result.

END OF MANAGEMENT TOOL